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NOTICE OF ALLOWANCE AND FEE(S) DUE

22852 7590 04/25/2002

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**CLASS-SUBCLASS**
1634	435-006000

DATE MAILED: 04/25/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,906	03/08/2000	Mark L. Collins	1147-0142	7923

TITLE OF INVENTION: TARGET AND BACKGROUND CAPTURE METHODS WITH AMPLIFCATION FOR AFFINITY ASSAYS

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
64	nonprovisional	NO	$1280	$0	$1280	07/25/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status.

A. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

B. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV. 07-01) Approved for use through 01/31/2004.

PART B - FEE(S) TRANSMITTAL

Complete and mail this form, together with applicable fee(s), to:

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MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

22852 7590 04/25/2002

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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64	nonprovisional	NO	$1280	$0	$1280	07/25/2002

EXAMINER	ART UNIT	CLASS-SUBCLASS
JOHANNSEN, DIANA B	1634	435-006000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47) attached.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

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Please check the appropriate assignee category or categories (will not be printed on the patent) ❑ individual ❑ corporation or other private group entity ❑ government

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❑ Issue Fee

❑ Publication Fee

❑ Advance Order - # of Copies _____

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❑ Payment by credit card. Form PTO-2038 is attached.

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The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

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UNITED STATES

EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/25/2002

Determination of Patent Term Extension or Adjustment under 35 U.S.C. 154 (b)

A reissue patent is for "the unexpired part of the term of the original patent." See 35 U.S.C. 251. Accordingly, the above-identified reissue application is not eligible for patent term extension or adjustment under 35 U.S.C.154(b).

PTOL-85 (REV. 07-01) Approved for use through 01/31/2004.

Notice of Allowability	Application No.	Applicant(s)	
	09/533,906	COLLINS ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *15 April 2002*.
2. ☒ The allowed claim(s) is/are *1-19,27-40,42-46,48-52,64-67,70-75 and 83-86*.
3. ☒ The drawings filed on *08 March 2000* are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Informal Patent Application (PTO-152)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
4☒ Interview Summary (PTO-413), Paper No. 31, 35, 36
5☒ Information Disclosure Statements (PTO-1449), Paper No. 27, 29
6☐ Examiner's Amendment/Comment
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8☐ Examiner's Statement of Reasons for Allowance
9☒ Other Attachment

ATTACHMENT TO NOTICE OF ALLOWABILITY

Papers entered.

1. Subsequent to the mailing of the Office action of paper no. 25 on February 12, 2002, the following papers have been entered:

a) The Supplemental Preliminary Amendment filed July 16, 2001, paper no. 26;

b) The Protest (with IDS) filed February 19, 2002, paper no. 27;

c) The Notice of Related Litigation filed February 21, 2002, paper no. 28;

d) The Supplemental IDS filed February 21, 2002, paper no. 29;

e) The Declaration of Andrew P. Feinberg filed February 21, 2002, paper no. 30;

f) The Interview Summary dated March 11, 2002, paper no. 31 (**copy provided herewith**);

g) The Amendment and surrendered Original Patent filed March 8, 2002, paper no. 32;

h) The Supplemental Reissue Declaration filed March 8, 2002, paper no. 34;

i) The Supplemental Amendment and Second Supplemental Reissue Declaration filed April 15, 2002, paper no. 33;

j) The Interview Summary dated April 2, 2002, paper no. 35 (**copy provided herewith**); and

k) The Interview Summary dated April 15, 2002, paper no. 36 (**copy provided herewith**).

Protest

2. It is noted that the Protest under 37 CFR 1.291(a) filed February 15, 2002, paper no. 27 ("the Second Protest"), has been considered. Further, all documents cited on the PTO Form 1449 included as part of paper no. 27 have been considered; an initialed and signed copy of that Form 1449 is included with this Office action.

3. It is noted that the response to the Second Protest filed by Applicants' March 8, 2002, as part of paper no. 32 ("the Response"), has been considered.

4. Each of the major points raised in the Second Protest are discussed below in the order set forth in the Second Protest. Please see the Interview Summary of paper no. 35 for additional discussion of issues raised by the Second Protest.

5. First, it is noted that Applicants have acknowledged that they consider December 12, 1987 to be the priority date to which they are entitled with respect to the pending claims (see Interview Summary, paper no. 12).

6. In Section 1 of the Second Protest, protestor asserts that all the claims pending in the instant reissue application are obvious under 35 U.S.C. 103.

(a) The protestor first argues that the combined teachings of Pollet et al (1967) and Feix et al (1968) render the claims obvious. It is acknowledged that the Pollet et al reference discloses a method of purifying phage QB minus strands, and that the Feix et al reference discloses "*in vitro* RNA synthesis using purified QB minus strands" in which the "*in vitro* reaction produces an increased amount of RNA," as argued by protestor. It is further acknowledged that the Feix et al reference relies on the Pollet et al for its teaching of QB minus strand preparation (see p. 146 of Feix et al), and that the isolation

method of Pollet et al comprises steps in which hybrids of minus strand target and plus strand fragments are bound to and subsequently eluted from a cellulose column (see page 767 of Pollet et al). However, the combined teachings of Pollet et al and Feix et al do not suggest the instant invention as now claimed. Applicants' broadest claim, claim 1, is drawn to a method for "amplifying a target polynucleotide contained in a sample" comprising steps of "(a) contacting the sample with a first support which binds to the target polynucleotide; (b) substantially separating the support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide; and (c) amplifying *in vitro* the separated target polynucleotide of (b)." Referring first to page 767 of the Pollet et al reference, Pollet et al teach a method in which a hybrid of target and other nucleic acid fragments is applied to a cellulose column and then eluted in hybrid form prior to subsequent separation and isolation of the minus strand. In contrast, the claims require "substantial separation" of "support and bound target polynucleotide" to produce a "separated target polynucleotide" that can immediately be subjected to *in vitro* amplification. Further, it is noted that the Feix et al reference discloses that prior to synthesis of RNA using QB minus strands as template, minus strands are prepared by the method of Pollet et al and then subjected to an additional "further purification step" comprising dialysis (p. 146). Accordingly, the combined teachings of Pollet et al and Feix et al do not teach a method having the advantages disclosed and claimed by applicants, in which a target bound to a support that has been "substantially separated" from sample may be immediately subjected to *in vitro* amplification without a requirement for additional steps such as separation of target

from the support. Thus, protestor's arguments are not persuasive. It is also noted that the combined teachings of Pollet et al and Feix et al do not suggest the other embodiments of applicants' invention encompassed by the claims, which embodiments are not addressed by the Second Protest (e.g., methods in which capture probes, retrievable supports, etc., are employed).

(b) Next, in Section 1(2), the Second Protest argues that "the pending claims are unpatentable as obvious over the disclosure of Chu et al., U.S. Patent No. 4,957,858." Protestor states that Chu et al teach that the *in vitro* amplification method of their invention "is typically carried out on a sample which is a processed specimen, derived from a raw specimen by various treatments," referring to column 7, lines 10-17, and that "the amplification method of the assay can be carried out on nucleic acids isolated from a specimen and deposited onto solid supports," referring to column 7, lines 24-38. Protestor's arguments with respect to the Chu et al reference are not persuasive. Protestor argues that "Chu et al. teach separation of the target polynucleotide from a sample by using a method that deposits the polynucleotide on a solid support, and nucleic acid amplification." First, the portion of Chu et al relied upon by Protestor, column 7, lines 24-38, refers to the application of isolated nucleic acids to solid supports, not to a process in which nucleic acids are isolated from a sample by binding to a solid support. Further, while Chu et al disclose and exemplify the application of total nucleic acids from a sample to a solid support (as (see, e.g., Examples XIV and XVI), as well as the isolation of a particular target molecule prior to application to a solid support (see, e.g., Example XVII), Chu et al do not disclose methods in which isolation

of a target molecule from a sample is accomplished by binding of that target to a solid support and substantially separating the target and support from the rest of the sample. Accordingly, Protestor's arguments are not persuasive.

(c) In Section 1(3), the Second Protest argues that "Signal amplification is within the scope of Applicant's definition of 'amplify' because it produces 'a molecule subject to detection steps in place of the target molecule, which molecules are created by virtue of the presence of the target molecule in the sample," and cites several references teaching detection involving signal amplification. These arguments are not persuasive. The term "amplify" as employed in the instant specification requires "creating an amplification product" as discussed at length in the Office action of paper no. 25. The amplified signals disclosed Dattagupta et al (US Patent No. 4,724,202), Dattagupta et al (US Patent No. 4,737,454), Schneider et al (U.S. Patent No. 4,882,269), and Stuart et al (U.S. Patent No. 4,732,847) are not amplification products, and therefore Protestor's arguments are not persuasive.

7. In Section 2 of the Second Protest, Protestor argues that Feix et al anticipate the claimed invention. However, the methods employed by Feix et al differ from the claimed invention for the reasons set forth in paragraph 5(a), above. Accordingly, Protestor's arguments are not persuasive.

8. In Section 3 of the Second Protest, Protestor argues that the Reissue Oath/Declaration is defective for failing to identify a specific error. This argument is moot in view of the submission by Applicant of a Supplemental Reissue Declaration on March 8, 2002, which Supplemental Reissue Declaration identifies a specific error.

9. In Section 4 of the Second Protest, Protestor argues that the Reissue Oath/Declaration is defective "because all of the inventors of the claimed invention may not have assigned all of their rights to the invention to Applicant, i.e., the Applicant who signed the oath may not have the 'entire interest' in the claimed invention". The Second Protest continues that "Protestor believes that there is a question about the correct inventorship of the application, as required by 35 U.S.C. 101 and 116, which names joint inventors." The Protestor asserts that a new oath/declaration signed by all inventors "may be required," and refers to three publications "that show that another person, Scott Decker, has been acknowledged by one of the named inventors in a manner that suggests that Scott Decker contributed to reduction to practice of the claimed invention." The three publications cited by Protestor are Morrissey & Collins (1989), which includes an acknowledgement of the contributions of "Scott Decker for adapting the PCR to our method of doing target capture;" Hunsaker et al (1989) which includes an acknowledgement of the contribution of "Scott Decker for showing how RTC and PCR can be successfully combined;" and Thompson et al (1989), of which Scott Decker is a co-author, and which Protestor asserts "shows the reduction to practice of the combination of RTC and PCR that the previous two cited papers acknowledge." It is first noted that none of the 3 references cited by Protestor constitute prior art with respect to the instant invention. MPEP 2137.01 states that "The party or parties executing an oath or declaration under 37 CFR 1.63 are presumed to be the inventors." Accordingly, the parties executing the original Oath/Declaration in the instant application are presumed to be the inventors, absent evidence to the contrary. Further, MPEP

2137.01 indicates that an inventor is one who contributes to conception of an invention. MPEP 2137.01 also indicates that an inventor need not actually carry out steps in the reduction to practice of an invention, and that one who carries out such steps is not an inventor unless he/she also contributes to conception of the invention. While the references cited by Protestor do suggest that Scott Decker was involved in reducing to practice an embodiment of applicants' invention, evidence of participation in the reduction to practice of an invention does not provide evidence of conception of that invention, which would be required to establish inventorship. Further, the Second Protest merely asserts that Scott Decker contributed to "reduction to practice," whereas the MPEP clearly indicates that the proper standard for establishing inventorship is not participation in reduction to practice, but rather contribution to conception of an invention. Accordingly, Protestor's arguments are not persuasive.

Declaration

10. The Declaration of Andrew P. Feinberg, M.D. filed February 21, 2002, paper no. 30, has been considered. The declaration is sufficient to establish that one of ordinary skill in the art could have carried out the embodiments of applicants' invention exemplified in Examples 5 and 6 and illustrated in Figures 5 and 6 without undue experimentation at the time the invention was made.

Notice of Related Litigation

11. The Notice of Related Litigation filed February 21, 2002, paper no. 28, has been considered. See the Interview Summary of paper no. 35 for a brief discussion of issues raised in the Notice of Related Litigation.

Supplemental IDS

12. The Supplemental IDS filed February 21, 2002, paper no. 29, has been considered with the exception of the two references cited thereon that are subject to a protective order. These two references were discussed on April 2, 2002 (see Interview Summary of paper no. 35). An initialed and signed copy of the PTO Form 1449 included with paper no. 29 is attached hereto.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
April 19, 2002

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER